UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,429	02/22/2002	William A. Haseltine	PF106P3D1	9565

22195 7590 06/10/2005

HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,429	HASELTINE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed January 27, 2003 is acknowledged and has been entered. Claims 15-21 have been added.

2. The preliminary amendment filed March 10, 2003 is acknowledged and has been entered.

3. The preliminary amendment filed February 23, 2004 is acknowledged and has been entered. Claims 22-60 have been added.

It is noted that the status of claim 18 is incorrect; the status of the claim is "Previously Presented", not "Currently Amended".

4. Claims 1-60 are pending in the application and are currently subject to restriction.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-4, 6, 7, 9-12, 15, and 16, insofar as the claims are drawn to a nucleic acid molecule, a vector comprising said nucleic acid molecule, a host cell comprising said vector, a method for producing a polypeptide comprising culturing said host cell, and a method for producing said host cell, wherein said nucleic acid molecule encodes a polypeptide having the deduced amino acid sequence of SEQ ID NO: 4, classified in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325+, and class 435, subclass 69.1.

Group II. Claims 1, 2, 5, 8-12, and 17, insofar as the claims are drawn to a nucleic acid molecule, a vector comprising said nucleic acid molecule, a host cell comprising said vector, a method for producing a polypeptide comprising culturing said host cell, and a method for producing said host cell, wherein said nucleic acid molecule encodes a polypeptide having the deduced amino acid

sequence of SEQ ID NO: 6, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325, or class 435, subclass 69.1.

Group III. Claim 13, insofar as the claim is drawn to a polypeptide having the deduced amino acid sequence of SEQ ID NO: 4, classified in class 530, subclass 350.

Group IV. Claim 13, insofar as the claim is drawn to a polypeptide having the deduced amino acid sequence of SEQ ID NO: 6, classified in class 530, subclass 350.

Group V. Claims 14, 22-34, 37-54, and 56-60, insofar as the claims are drawn to an antibody that binds a polypeptide having the deduced amino acid sequence of SEQ ID NO: 4 and a cell or hybridoma that produces said antibody, classified, for example, in class 530, subclass 387.9.

Group VI. Claim 14, insofar as the claim is drawn to an antibody that binds a polypeptide having the deduced amino acid sequence of SEQ ID NO: 6 and a cell or hybridoma that produces said antibody, classified, for example, in class 530, subclass 387.9.

Group VII. Claims 18, 19, and 21, insofar as the claims are drawn to a method for diagnosing a susceptibility to cancer comprising determining the presence of a mutation in a gene comprising the polynucleotide sequence of a polynucleotide encoding a polypeptide encoded by the cDNA of ATCC Deposit No. 75649 or ATCC Deposit No. 75651, classified in class 435, subclass 6.

Group VIII. Claims 20 and 21, insofar as the claims are drawn to a method for diagnosing a susceptibility to cancer comprising determining the presence of a mutation in a gene comprising the polynucleotide sequence of a polynucleotide

encoding a polypeptide encoded by the cDNA of ATCC Deposit No. 75650, classified in class 435, subclass 6.

Group IX. Claims 35, 36, and 55, drawn to a method for detecting a protein having the amino acid sequence of SEQ ID NO: 4 comprising contacting a sample with an antibody that binds said protein, classified, for example, in class 435, subclass 7.1.

6. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VI include patentably distinct products; and the inventions of Groups I, II, and VII-IX include patentably distinct processes.

The products of Groups I-VI are patentably distinct, each from the other, because the products of Groups I and II are nucleic acid molecules encoding a polypeptide having the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6, respectively, or vectors or host cells comprising said nucleic acid molecules, the products of Group III and IV are polypeptides having the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6, respectively, and the products of Groups V and VI are antibodies that bind a polypeptide having the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6, respectively.

The products of Groups I and II are patentably distinct, since, although both are nucleic acids, vectors, or host cells, the nucleic acids, vectors, or host cells comprise structurally and functionally distinct polynucleotide sequences encoding structurally and functionally distinct polypeptides. Because the products of Groups I and II comprise structurally and functionally distinct polynucleotide sequences encoding structurally and functionally distinct polypeptides, the search required to examine claims drawn to either invention is not the same, nor is it coextensive with the search required to examine claims drawn to the other. Accordingly, each group would require a unique search and having to perform more than one search would be unduly burdensome. See MPEP § 803.

Similarly, the products of Groups III and IV are patentably distinct, since, although both are polypeptides, the polypeptides are structurally and functionally distinct, comprising unique amino acid sequences. Because the products of Groups III and IV comprise distinct amino acid

sequences, the search required to examine claims drawn to either invention is not the same, nor is it coextensive with the search required to examine claims drawn to the other. Accordingly, each group would require a unique search and having to perform more than one search would be unduly burdensome. See MPEP § 803.

Similarly, the products of Groups V and VI are patentably distinct, since, although both are antibodies, the antibodies bind to structurally and functionally distinct polypeptides that comprise unique amino acid sequences. Because the products of Groups V and VI are antibodies that bind to polypeptide comprising distinct amino acid sequences, the search required to examine claims drawn to either invention is not the same, nor is it coextensive with the search required to examine claims drawn to the other. Accordingly, each group would require a unique search and having to perform more than one search would be unduly burdensome. See MPEP § 803.

Furthermore, olypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different

from the claimed inventions. Therefore, the inventions of Groups I and II and the invention of Groups III and IV are patentably distinct products.

The inventions of Groups I and II and the invention of Groups III and IV have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Groups I or II would not suffice to provide adequate information regarding the merit of the claims of Groups III or IV, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I or II and the inventions of Groups III ad IV, an examination of any two would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Groups I and II and the inventions of Groups III and IV are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups III and IV and the inventions of Groups V and VI are patentably distinct because, although both are polypeptides, the inventions of Groups III and IV are globular proteins, whereas the inventions of Groups V and VI are antibodies. An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, the polypeptide of Groups III and IV are disclosed as consisting of a single polypeptide chain; so the inventions of Groups III and IV and the inventions of Groups V and VI

are structurally distinct from one another. Moreover, the primary structures (i.e., amino acid sequences) of which the inventions are comprised are not the same, nor similar. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups III and IV and the inventions of Groups V and VI are patentably distinct products.

Searching more than one of the inventions of Groups III and IV and the inventions of Groups V and VI would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words.

Therefore, having to search an invention of Groups III and IV and an invention of Groups V and VI would constitute a serious burden.

Since the inventions of Groups III and IV and the inventions of Groups V and VI are patentably distinct from the others and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups I and II and the inventions of Groups V and VI are patentably distinct because a polynucleotide and an antibody are chemically distinct molecules, since a polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, the inventions of Groups I and II and the inventions of Groups V and VI are patentably distinct products.

Searching more than one of the inventions of Groups I or II and the inventions of Groups V or VI would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search an invention of Groups I or II and an invention of Groups V or VI would constitute a serious burden.

Since the inventions of Groups I and II and the inventions of Groups V and VI are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The processes of Groups I, II, and VII-IX are patentably distinct, each from the other, because the processes of Groups I and II are methods for producing a host cell or a polypeptide, the processes of Groups VII and VIII are methods for diagnosing a susceptibility to cancer, and the processes of Group IX are methods for detecting a polypeptide. Accordingly, the processes of Groups I and II, the processes of Groups VII and VIII, and the processes of Group IX are

materially different processes comprising different process steps, having different objectives, different endpoints, and different criteria for success.

The processes of Groups I and II are patentably distinct, since, although both are methods for producing a host cell or a polypeptide, the host cells comprise structurally and functionally distinct polynucleotide sequences encoding structurally and functionally distinct polypeptides and the polypeptides are structurally and functionally distinct, comprising unique amino acid sequences. Accordingly, the search required to examine claims drawn to either invention is not the same, nor is it coextensive with the search required to examine claims drawn to the other. Therefore, each group would require a unique search and having to perform more than one search would be unduly burdensome. See MPEP § 803.

The processes of Groups VII and VIII are patentably distinct, since, although both are methods for diagnosing a susceptibility to cancer, the processes comprise distinct steps that determine the presence of a mutation in structurally and functionally distinct genes comprising unique polynucleotide sequences and encoding structurally and functionally distinct polypeptides, comprising unique amino acid sequences. Accordingly, the search required to examine claims drawn to either invention is not the same, nor is it coextensive with the search required to examine claims drawn to the other. Therefore, each group would require a unique search and having to perform more than one search would be unduly burdensome. See MPEP § 803.

The inventions of Groups I-IV and VI and the inventions of Group IX are unrelated because the products of Groups I-IV and VI are not specifically used or otherwise involved in the processes of Group IX.

The inventions of Groups I-VI and the inventions of Groups VII and VIII are unrelated because the products of Groups I-VI are not specifically used or otherwise involved in the processes of Groups VII and VIII.

The inventions of Groups III-VI and the inventions of Groups I and II are unrelated because the products of Groups III-VI are not specifically used or otherwise involved in the processes of Groups I and II.

The inventions of Group V and the inventions of Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely an antibody can be used in a materially different process of using that product, such as the process of purifying the protein to which the antibody binds by affinity chromatography.

7. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
June 8, 2005